Vaccine News and Previews Part 2

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Disclosures

- The speaker is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation
- The speaker will discuss the off-label use of MMR, meningococcal conjugate vaccine, and HPV vaccines
- The speaker will not discuss a vaccine not currently licensed by the FDA

Objectives

- Increase provider knowledge regarding immunizations and the importance of promoting immunizations in the community.
- Explain at least one recent change to immunization recommendations from the Advisory Committee on Immunization Practices (ACIP)

Overview

- Influenza update
- Measles update and MMR for children 6-11 months of age traveling outside the U.S.
- Hepatitis A clarification for timing of 2nd dose
- Expansion of meningococcal conjugate vaccine recommendations
- HPV for males
- Herpes zoster age indications
- Immunization of healthcare personnel
- Best Practices for Vaccine S&H and Administration

Influenza

www.cdc.gov/vaccines/pubs/ACIP-list.htm#flu
www.cdc.gov/vaccines/pubs/pinkbook/downloads/flu.pdf
www.cdc.gov/vaccines/pubs/vis/downloads/vis-flu.pdf
www.cdc.gov/vaccines/pubs/vis/downloads/vis-flulive.pdf
www.immunize.org/askexperts/experts_inf.asp

Influenza Activity Update

- The United States is experiencing a late flu season
- In addition to seeing the season start late, flu seasons also have peaked late. In the past 35 seasons, we have seen activity peak 4 times in March and two times in April
- At this rate, we may continue to see flu activity in the United States for some time
- If you haven't gotten vaccinated yet, get your vaccine now
- More than 132.1 million doses of vaccine had been delivered in the United States as of early February 2012

Influenza Activity Update

- Influenza viruses are constantly changing and it's impossible to say what the "vaccine match" will be for this influenza season at this time.
- So far, cumulatively, most of the influenza viruses tested at CDC this season are well-matched to the vaccine viruses.

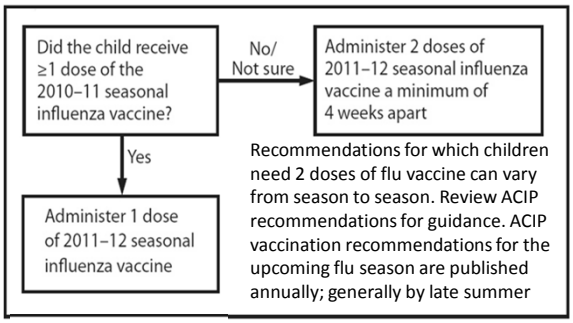
Influenza Activity Update

- In recent weeks, however, there has been an increasing proportion of influenza B viruses that are from another lineage of B viruses than is in the vaccine. Influenza B viruses are divided into two lineages: B/Victoria and B/Yamagata viruses. The current vaccine protects against a B/Victoria virus.
- In addition, the percentage of influenza A (H3N2) viruses that are said to be "low reactors" to the H3N2 vaccine virus has increased. Low reactors are viruses that don't respond to vaccine antibodies as well, but some cross-protection is expected.

Universal Recommendation

- Influenza vaccine is recommended for everyone 6 months and older (without contraindications to the vaccine)
- Keep vaccinating

Influenza vaccine dosing algorithm for children aged 6 months through 8 years — Advisory Committee on Immunization Practices (ACIP), 2011–12 influenza season



Recommendations for which children need 2 doses of flu vaccine can vary from season to season. Review ACIP recommendations for guidance. ACIP vaccination recommendations for the upcoming flu season are published annually; generally by late summer

MMWR 2011;60(33):1128-32

Pregnant Women, Newborns, and Influenza Vaccination

- Pregnant women are at increased risk of complications of influenza
  - women who are or will be pregnant during influenza season should receive influenza vaccine (TIV only)
- Infants younger than 6 months of age are at very high risk of complications and hospitalization from influenza
  - no vaccine is available for infants younger than 6 months

MMWR 2010;59(RR-8)

Effectiveness of Influenza Vaccination of Pregnant Women in Reducing Hospitalization of Infants

	Cases	Controls
Mother vaccinated	2 (2%)	31 (20%)
Mother unvaccinated	89 (98%)	21 (80%)
Vaccine Effectiveness	92%	

Cases were children younger than 6 months of age hospitalized with culture-confirmed influenza.
Clin Infect Dis 2010;51:1355-61

Influenza Vaccine Strains for 2012-13 Season

- A/California/7/2009 (H1N1)pdm09, pandemic strain
- A/Victoria/361/2011 (H3N2)-replaces A/Perth/16/2009
  - Almost all of the recent "low reactor" H3N2 viruses are well matched to the 2012-2013 H3N2 vaccine component selected
- B/Wisconsin/1/2010-replaces B/Brisbane/60/2008
  - Yamagata lineage

Test Your Knowledge

- If an unvaccinated patient who has just recovered from a diagnosed case of influenza comes into your clinic, should you vaccinate him?

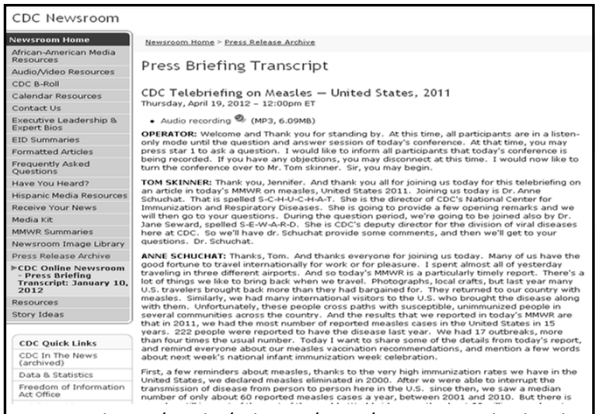
MEASLES

www.cdc.gov/vaccines/pubs/ACIP-list.htm#mmr
www.cdc.gov/vaccines/pubs/pinkbook/downloads/meas.pdf
www.cdc.gov/vaccines/pubs/pinkbook/downloads/mumps.pdf
www.cdc.gov/vaccines/pubs/pinkbook/downloads/rubella.pdf
www.cdc.gov/vaccines/pubs/vis/downloads/vis-mmr.pdf
www.cdc.gov/vaccines/pubs/vis/downloads/vis-mmrv.pdf
www.immunize.org/askexperts/experts_mmr.asp

U.S. Measles Epidemiology in the Post Elimination Era

Year	Reported Cases
2011	**222**
2010	63
2009	71
2008	140
2007	42
2006	55

*Provisional data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CDC Online Newsroom – Press Briefing Transcript: January 10, 2012
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CDC In The News (archived)
Data & Statistics
Freedom of Information Act Office

Newsroom Home > Press Release Archive

Press Briefing Transcript

CDC Telebriefing on Measles — United States, 2011
Thursday, April 19, 2012 – 12:00pm ET

- Audio recording (MP3, 6.09MB)

OPERATOR: Welcome and Thank you for standing by. At this time, all participants are in a listen-only mode until the question and answer session of today's conference. At that time, you may press star 1 to ask a question. I would like to inform all participants that today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to Mr. Tom skinner. Sir, you may begin.

TOM SKINNER: Thank you, Jennifer. And thank you all for joining us today for this telebriefing on an article in today's MMWR on measles, United States 2011. Joining us today is Dr. Anne Schuchat. That is spelled S-C-H-U-C-H-A-T. She is the director of CDC's National Center for Immunization and Respiratory Diseases. She is going to provide a few opening remarks and we will then go to your questions. During the question period, we're going to be joined also by Dr. Jane Seward, spelled S-E-W-A-R-D. She is CDC's deputy director for the division of viral diseases here at CDC. So we'll have dr. Schuchat provide some comments, and then we'll get to your questions. Dr. Schuchat.

ANNE SCHUCHAT: Thanks, Tom. And thanks everyone for joining us today. Many of us have the good fortune to travel internationally for work or for pleasure. I spent almost all of yesterday traveling in three different airports. And so today's MMWR is a particularly timely report. There's a lot of things we like to bring back when we travel. Photographs, local crafts, but last year many U.S. travelers brought back more than they had bargained for. They returned to our country with measles. Similarly, we had many international visitors to the U.S. who brought the disease along with them. Unfortunately, these people cross paths with susceptible, unimmunized people in several communities across the country. And the results that we reported in today's MMWR are that in 2011, we had the most number of reported measles cases in the United States in 15 years. 222 people were reported to have the disease last year. We had 17 outbreaks, more than four times the usual number. Today I want to share some of the details from today's report, and remind everyone about our measles vaccination recommendations, and mention a few words about next week's national infant immunization week celebration.

First, a few reminders about measles, thanks to the very high immunization rates we have in the United States, we declared measles eliminated in 2000. After we were able to interrupt the transmission of disease from person to person here in the U.S. since then, we saw a median number of only about 60 reported measles cases a year, between 2001 and 2010. But there is

www.cdc.gov/media/releases/2012/t0419_measles.html

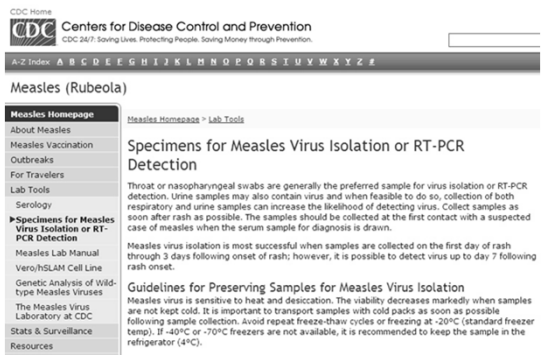
MMR Vaccination of Infants

- 6-11 month old infants accounted for 13% of reported measles cases during 2001-2011
- Many infants infected during international travel or following contact with a traveler
- Recommendation for MMR vaccination of 6-11 month olds* added to the annual schedule in 2012

*this dose does not count as part of the MMR schedule. Repeat dose at 12-15 months of age. *MMWR* 2012;61(5)

Measles in the United States

- Ensure all patients are up to date on MMR vaccine and other vaccines
- Consider measles if
  - —febrile rash illness lasting 3 days or more
  - —temperature of 101ºF (38.3ºC) or higher
  - —cough, coryza, and/or conjunctivitis
  - —recently traveled abroad or
  - —had contact with someone with a febrile rash illness



www.cdc.gov/measles/lab-tools/rt-pcr.html

Test Your Knowledge

- If an infant receives a dose of MMR vaccine for international travel before 12 months of age, how many more doses of MMR are indicated and when should they be administered?

HEPATITIS A

www.cdc.gov/vaccines/pubs/ACIP-list.htm#hepa
www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepa.pdf
www.cdc.gov/vaccines/pubs/vis/downloads/vis-hep-a.pdf
www.immunize.org/askexperts/experts_hepa.asp

Hepatitis A Vaccination Schedule

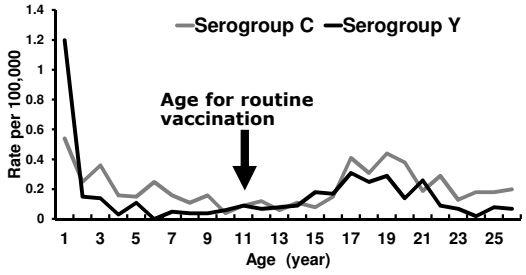
- ACIP recommends routine hepatitis A vaccination at 12-23 months of age
  - minimum interval between doses is 6 calendar months
- Depending on age of first dose it may not be possible to meet the minimum interval and complete the series by 23 months of age
- In 2012 ACIP clarified that the hepatitis A vaccine schedule could be completed at older than 23 months of age

MMWR 2012;61(5)

N. Meningitidis

www.cdc.gov/vaccines/pubs/ACIP-list.htm#mening
www.cdc.gov/vaccines/pubs/pinkbook/downloads/mening.pdf
www.cdc.gov/vaccines/pubs/vis/downloads/vis-mening.pdf
www.immunize.org/askexperts/experts_men.asp

Rates of Meningococcal Disease (C and Y) by Age, 1999-2008



Active Bacterial Core surveillance (ABCs), 1998-2008

Meningococcal Conjugate Vaccines

- Menactra
  - approved in January 2005 for a single dose among persons 2 through 55 years of age
  - approved in April 2011 for a two-dose series for children 9-23 months of age
- Menveo
  - approved in February 2010 for a single dose among persons 2 through 55 years of age

Meningococcal Conjugate Vaccine (MCV4) Issues

Issue	Solution
• Inadequate response to a single dose of MCV4	• Routine 2-dose primary series
• Waning immunity following 1 dose of MCV4	• Revaccination of some MCV4 recipients
• Routine vaccination of infants	• Vaccination of high-risk; routine vaccination being considered

Persons at Highest Risk of Meningococcal Disease or Suboptimal Vaccine Response

- Complement deficiency
  - very high antibody titer required to compensate for complement deficiency
- Asplenia
  - evidence of suboptimal response
- Single dose primary series may not be sufficient to confer protection for persons with these high-risk conditions

New MCV4 Recommendations

- Administer 2 doses* of MCV4 at least 8 weeks apart to persons with persistent complement component deficiency and anatomic or functional asplenia, and 1 dose every 5 years* thereafter

* off-label recommendations. *MMWR* 2011;60(No. 3):72-6.

MCV4 Recommendations and HIV

- HIV infection alone is not an indication for MCV4 vaccination
- Persons with HIV infection show evidence of suboptimal response to vaccination
- Some persons with HIV infection should receive MCV4 (adolescents, some international travelers, microbiologists, etc)
- Persons with HIV infection who are vaccinated with MCV4 should receive 2 doses at least 8 weeks apart*

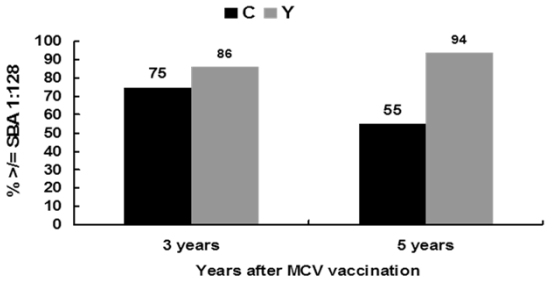
*off-label recommendation. *MMWR* 2011;60(No. 3):72-6.

MCV4 Revaccination

- In its 2005 recommendations for MCV, ACIP made no recommendation about revaccination pending the availability of additional data
- Serologic data are now available that show significant decline in antibody 3-5 years after vaccination although few "breakthrough" cases have been reported

MMWR 2009;58(No. 37):1042-3

Seroprotection Rates Following MCV Vaccination



MMWR 2009;58(No. 37):1042-3

Routine Adolescent MCV4 Vaccination*

- Administer MCV4 at age 11 or 12 years with a booster dose at 16 years of age
- Administer 1 dose at age 13 through 15 years if not previously vaccinated
- For persons vaccinated at age 13 through 15 years administer a 1-time booster dose is recommended, preferably at or after 16 through 18 years of age

**off-label recommendation. *MMWR* 2011;60(No. 2):72-6.

Routine Adolescent MCV4 Vaccination

- The minimum interval between doses is 8 weeks
- A booster dose is not recommended for healthy persons if the first dose is administered at 16-21 years of age
- A booster dose is not recommended for healthy persons 22 years or older even if the first dose is administered at 11-15 years of age
- The booster dose should always be MCV4 (not MPSV4)

***MMWR* 2011;60(No. 2):72-6.**

Meningococcal Vaccination of Children 9-23 Months of Age*

- In April 2011 FDA approved Menactra for children as young as 9 months
- ACIP recommends Menactra for high-risk children 9 through 23 months of age
  - 2-dose series
  - 3-month interval between doses
  - administer at 9 and 12 months of age (minimum interval 2 months)

MMWR 2011;60(No.40):1391-2

Meningococcal Vaccination of Children 9-23 Months of Age*

- ACIP defines high-risk children age 9 through 23 months as:
  - those with persistent complement component deficiency
  - those in a community or institution where a meningococcal disease outbreak is occurring, or
  - those traveling to an area of the world where meningococcal disease is epidemic

MMWR 2011;60(No.40):1391-2

Meningococcal Vaccination of Children with Asplenia

- Data suggest a reduction in response to PCV13 if given at the same visit as MCV4
- Asplenic persons are at very high risk of invasive pneumococcal disease
- The minimum age for meningococcal vaccination of children with asplenia (including those with sickle cell disease) remains 2 years
- Separate PCV13 and MCV4 by at least 4 weeks

MMWR 2011;60(No.40):1391-2

Test Your Knowledge

- What is the minimum interval between a dose of MCV4 and a dose of PPSV23?

Human Papillomavirus

www.cdc.gov/vaccines/pubs/ACIP-list.htm#hpv
www.cdc.gov/vaccines/pubs/pinkbook/downloads/hpv.pdf
www.cdc.gov/vaccines/pubs/vis/downloads/vis-hpv-gardasil.pdf
www.cdc.gov/vaccines/pubs/vis/downloads/vis-hpv-cervarix.pdf
www.immunize.org/askexperts/experts_hpv.asp

HPV Disease Burden Among Males in the United States

- Estimated 22,000 HPV 16- and 18-associated cancers occur annually in the United States
  - 7,000 of these occur in males, primarily anal, penile and oropharyngeal cancers
- Approximately 250,000 cases of genital warts caused primarily by HPV types 6 and 11 occur annually in the United States among sexually active males
- Transmission to female contacts?

MMWR 2011;60(No.20):1705-8

HPV Vaccines

- HPV4 (Gardasil, Merck)
  - contains HPV types 16, 18, 6 and 11
  - approved for the prevention of
    - cervical, vaginal and vulvar cancers in females
    - anal cancers and genital warts in females and males
- HPV2 (Cervarix, GlaxoSmithKline)
  - contains HPV types 16 and 18
  - approved for the prevention of cervical cancers in females

HPV Vaccine Efficacy - Males*

Endpoint	Efficacy
HPV 6/11/16/18 related genital warts	89%
HPV 6/11/16/18 related AIN 1/2/3	78%

*Among 16-26 year old males. AIN – anal intraepithelial neoplasia.
Manufacturer data submitted to FDA

HPV4 Vaccine Recommendations for Males

- Only HPV4 (Gardasil) should be administered to males
  - HPV2 is not approved for males of any age
- Routinely administer HPV4 to males 11 to 12 years of age to prevent HPV infection and HPV-related diseases
  - May be administered as young as 9 years of age
- Catch-up: Administer HPV4 to males 12 through 21 years of age who have not completed an HPV4 series

MMWR 2011;60(No.20):1705-8

HPV Vaccine Special Situations - Males

- Immunosuppression
  - ACIP recommends routine vaccination with HPV4 for all immunosuppressed males (including HIV infection) through 26 years of age*
- Men who have sex with men (MSM)
  - ACIP recommends routine vaccination with HPV4 for all MSM through 26 years of age*

*who have not been vaccinated previously or who have not completed the 3-dose series. *MMWR* 2011;60(No.50):1703-8.

HPV Vaccination Schedule

- Recommended schedule is 0, 1-2, 6 months
  - following the recommended schedule is preferred
- Minimum intervals
  - 4 weeks between doses 1 and 2
  - 12 weeks between doses 2 and 3
  - 24 weeks between doses 1 and 3
- Administer at the same visit as other age-appropriate vaccines – Tdap, MCV4, influenza

MMWR 2007;56(RR-2):1-24

HPV Vaccine Intervals

- There are no MAXIMUM intervals between HPV vaccine doses
- If the interval between doses is longer than recommended the series should be continued where it was interrupted
- Do not re-start a valid, documented series

MMWR 2011;60(RR-2):10

National Immunization Survey – Teen 2010

HPV Immunization Rates*13-17 years of age

HPV vaccine	U.S.	AZ
1 or more doses	48.7%	52.8%
3 dose series completion **	69.6%	67.0%

*Percentages ≥1 human papillomavirus vaccine, either HPV4 or HPV2 reported among females only (n=9,220)

** Percentage of females who received 3 doses among those who had at least 1 HPV dose and at least 24 weeks between the first dose and interview date.

MMWR 2011; 60 (No. 33):1117-11123

HPV Series Completion

- Significant number of girls who began the HPV series do not receive all three doses
- Related factors include:
  - Parents often lack awareness of the importance of vaccinating preteen girls
  - Not receiving a strong recommendation for HPV vaccination from healthcare providers
- Incorporate measures to improve vaccination rates
  - Strongly recommend HPV vaccine
  - Reminder/recall
  - Standing orders/vaccine only visits
  - Report to TWIS

Test Your Knowledge

- If a male patient receives a dose of HPV2 at another facility, and now presents at a clinic that only stocks HPV4, how should the series be completed?
- If a female patient receives a dose of HPV2 at another facility, and now presents at a clinic that only stocks HPV4, how should the series be completed?

Herpes zoster

www.cdc.gov/vaccines/pubs/ACIP-list.htm#zoster
www.cdc.gov/vaccines/pubs/pinkbook/downloads/varicella.pdf
www.cdc.gov/vaccines/pubs/vis/downloads/vis-shingles.pdf
www.immunize.org/askexperts/experts_zos.asp

Zoster Vaccine

- Now licensed for adults 50-59 years of age
- Routine vaccination of adults younger than 60 years NOT recommended by ACIP
- Rationale
  - reduced supply
  - burden of complications highest in persons older than 60 years

Test Your Knowledge

- What is the minimum interval between a dose of PPSV23 and zoster vaccine?
- What is the minimum interval between a dose of varicella vaccine and a dose of zoster vaccine?

Immunization of Healthcare Personnel

www.cdc.gov/mmwr/pdf/rr/rr6007.pdf

Vaccine Storage & Handling Best Practices

- Maintain written routine and emergency vaccine storage & handling plans
- Designate storage & handling responsibilities to a primary vaccine coordinator and at least one back-up coordinator
- Provide orientation, training, and continuing education regarding proper storage & handling practices for all personnel (permanent & temporary) who will have access to vaccines
- Ensure vaccine storage units and other equipment are in good working order and able to maintain the proper temperatures
- Store vaccines and diluents within the proper temperature ranges and protect them from light as recommended by the manufacturer
- Read & document storage unit temperatures at least twice each workday
- Take preventive measures to protect the power supply to vaccine storage units
- Rotate stock so that vaccine closest to its expiration date will be used first and monitor expiration dates to ensure that expired vaccine is removed from the storage unit(s) and not administered to patients
- Take immediate corrective action when there is a temperature excursion

http://www.cdc.gov/vaccines/recs/storage/default.htm

Vaccine Administration Best Practices

- Assess the immunization record
- Use the current recommended immunization schedules
- Screen for contraindications and precautions
- Educate the parent and/or patient, using Vaccine Information Statements and other credible resources
- Administer vaccine(s) using best practice guidelines, the rights of medication administration, and measures to minimize discomfort and promote safety
- Implement protocols to manage an acute adverse reaction should it occur
- Document what you did, using immunization information systems (registries) whenever available
- Provide the patient with a copy of their immunization record

http://www.cdc.gov/vaccines/recs/vac-admin/default.htm

The Future???

- ACIP discussions, but NO recommendation as yet
  - PCV13 use in adults 50 yrs and older
  - Meningococcal vaccine for infants
  - Use of third dose of MMR vaccine in outbreaks
  - Quadrivalent influenza vaccine

CDC Vaccines and Immunization Contact Information

- Telephone 800.CDC.INFO
  (for patients and parents)
- Email nipinfo@cdc.gov
  (for providers)
- Website www.cdc.gov/vaccines/
- Vaccine Safety www.cdc.gov/vaccinesafety/